REMARKS

The Examiner states that the oath or declaration is defective because the section under claim to benefit of earlier U.S. application(s) under 35 U.S.C. § 120 indicates that there are no earlier applications to which Applicants are claiming priority. However, on page 1 of the specification under "Cross-Reference to Related Application", priority to U.S. Application Serial No. 08/829,854 is claimed, a new declaration is required and thus, Applicant hereby submits an unexecuted corrected oath and will submit an identical executed corrected oath as soon as possible.

Claims 15, 17 and 18 are rejected by the Examiner under 35 U.S.C. § 101 as being drawn to nonstatutory subject matter because claim 15 is drawn to an organism or cell, *per se,* which is a product of nature, and therefore not patentable under 35 U.S.C. § 101. The Examiner suggest that applicants use the language "purified" in connection with the CS194 polynucleotide or fragment thereof to identity a product that is not found in nature. Similarly, the Examiner states that claims 17 and 18 read on products of nature, and are therefore not patentable under 35 U.S.C. § 101. It is also suggested that applicants use the language "purified" in connection with the gene or fragement thereof to identity a product that is not found in nature.

Applicant has amended the claims as the Examiner suggested thereby obviating this rejection.

Claims 1-6, 11, 15, 17 and 18 are also rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Thus, Applicant has amended the claims to omit the "CS194 gene" language thereby obviating this rejection.

The Examiner further states that, in addition, claims 4 and 11 are directed to polynucleotides which comprise a sequence encoding at least one CS194 epitope, and admits that the specification does define the term "epitope" as an antigenic determinant of a polypeptide or protein. However, the Examiner alleges that the specification fails to disclose any particular seuence which may encode an epitope, nor does the specification identify nucleic acid sequences encoding three, five or either to ten amino acids which are antigenic determinants.

Applicant respectfully, yet vigorously, disagrees. The method for identifying epitopes in a novel peptide sequence are well known and described in both the scientific, commercial, and patent literature. For example, M. H. VanRegenmortel describes how to predict epitopes from the primary sequence of a protein. (See "Protein structure and antigenicity", *Int J Rad Appl Instrum B.*, **14(4):**277-280, (1987).)

Perkin-Elmer Biosystems, a major provider of DNA sequencing and peptide synthesizing instrucments has established a public website which describes how to select peptides which reflect the epitopes of a proten. (See http://www.pebio.com/pa/340913/html/chapt2.html#Choosing the Epitope.) This electronic publication was posted in 1996 and basically describes the process employed by the inventors of the current patent application.

Patent application PCT/UYS97/00485 describes in detail how to identify epitopes from epptide sequences. The sequence can be scanned for hydrophobicity and hydrophilicity values by the method of Hopp, Prog. Clin. Biol. Res. 172B:367-377 (1985) or the method of Cease, *et al.*, J. Exp. Med. 164:1779-1784 (1986) or the method of Spouge, *et al., J. Immunol.*, **138:**204-212 (1987). Commercial software programs to implement these methods are available. Based on the aforementioned, applicant requests that this rejection be withdrawn.

Claims 1-6, 11, 15, 17 and 18 are also are rejected under 35 U.S.C. § 112, first paragraph, because the specification, which being enabling for the nucleic acid sequences set forth in the claimed SEQ ID NOS., does not reasonable provide enablement for nucleic acid sequences which are capable of selectively hybridizing to the nucleic acid of the CS194 gene and which have at least 50% identity with a sequence selected from the group consisting of SEQ ID NOS. 1-20, and fragments or complements thereof.

Therefore, Applicant submits the software manual to the Wisconsin Sequence Analysis program, Version 8, publicly available from Genetics Computer Group, Madison, WI, as Exhibit A. Support for this submission is found on page 12, beginning on line 10. The manual provides the algorithm, parameters, parameter values and other information necessary to, accurately and consistently, calculate the percent identity. This manual indicates on pages 5-21, *inter alia,* that the software used the local homology algorithm of Smith and Waterman (Advances in Applied Mathematics 2; 482-489 (1981)).

Further, Applicant has amended the claims to omit "selectively hybridizing" and "fragment" language. Thus, rejections based on this language are obviated.

The Examiner further states that, in addition, the specification does not reasonable provide enablement for nucleic acid sequences which encode epitopes of CS194. However, based on the aforementioned statements made by Applicant relating to epitope language, this rejection is deemed moot.

Claims 1-3, and 5 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner states claim 1 is rendered vague and indefinite for the following reasons; the phrase "is capable of selectively hybridizing to the nucleic acid of said CS194 gene". This rejection is deemed moot, since Applicant has omitted this language from claim 1.

The Examiner further states that claims 1 and 5 are rendered vague and indefinite by the pharase "derived from" as it is unclear how an open reading frame can be derived from "CS194". This rejection is also deemed moot since this language has also been omitted from the claims.

The Examiner also rejects claims 1-3, 5, 6, 15 and 18 under 35 U.S.C. § 102(e) as being anticipated by Yu, *et al.,* (U.S. patent No. 5,733,748, 1998, filing date June 6, 1995. However, due to the fact that the Applicant has amended the claims in order to delete "fragment" language, raised the percent identity to 70% with respect to SEQ ID NOS. 9, 13, and 14, and deleted "selectively hybridizing" language, this rejection is deemed moot.

Claims 1, 2, 5, 6, 15 and 18 are also rejected under 35 U.S.C. § 102(b) as being anticipated by Cunningham, *et al.,* (J. Biol. Chem., **270:**52, 31016-31026, 1995).

Again, due to the fact that the Applicant has amended the claims in order to delete "fragment" language, raise the percent identity to 70% with respect to SEQ ID NOS. 9, 13, and 14, and deleted "selectively hybridizing" language, this rejection is deemed moot.

Claims 1, 2, 15, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Okubo, *et al.,* (GenBank Acc. No. D-24725, 1995). Again, due to the fact that the Applicant has amended the claims in order to delete "fragment" language, raise the percent identity to 70% with respect to SEQ ID NOS. 9, 13, and 14, and deleted "selectively hybridizing" language, this rejection is deemed moot.

Claims 1-3, 5, 6, 15 and 18 are further rejected under 35 U.S.C. § 102(b) as being anticipated by various Hillier, Waterston, Burnett and Kohara references.

Again, due to the fact that the Applicant has amended the claims in order to delete "fragment" language, raise the percent identity to 70% with respect to SEQ ID NOS. 9, 13, and 14, and deleted "selectively hybridizing" language, this rejection is deemed moot.

CONCLUSION

In view of the aforementioned amendments and remarks, the aforementioned application is in condition for allowance and Applicant requests that the Examiner withdraw all outstanding objections and rejections and to pass this application to allowance.

Respectfully submitted,

P. A. Billing-Medel, *et al.*

Abbott Laboratories
D377/AP6D-2
100 Abbott Park Road
Abbott Park, IL 60064-6050
(847) 935-7550
Fax: (847) 938-2623

Mimi C. Goller
Registration No. 39,046
Attorney for Applicants